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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,848	09/14/2000	Robert Terkeltaub	660088.441	1635

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,848

Applicant(s)

TERKELTAUB ET AL.

Examiner

Konstantina Katcheves

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 11-15 are pending in the present application. This office action is in response to Paper No. 9, filed 3 February 2003.

Election/Restrictions

Applicant's election without traverse of Group C, claims 3-5 and 8-15 in Paper No. 9 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,

- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Nature of the invention and breadth of the claims

Applicant's claims are directed to a method for screening agents useful in the prevention or treatment of osteoarthritis. Applicant's method comprises steps, which include comparing the rate of ATP synthesis in one or more biological samples from a cow in the presence of or absence of a test agent. The altered rate of ATP synthesis indicates that the test agent is useful for treating osteoarthritis.

Applicant's method asserts that assessing the rate of ATP synthesis of cells, specifically chondrocytes and hematopoietic cells, in the presence of a test agent correlates to the therapeutic value of said test agent for treating a cow "suspected of being at risk for having" osteoarthritis. Thus, Applicant asserts that therapeutics useful in the treatment of osteoarthritis may be identified. Applicant's method seeks to identify compounds useful for osteoarthritis in a cow by assessing mitochondrial function by measuring the rate of ATP synthesis.

Guidance provide and presence of working examples in the specification

To identify compounds useful for treating osteoarthritis, Applicant must establish a nexus between mitochondrial activity including ATP synthesis and the treatment of osteoarthritis in a cow. However, Applicant has not shown any such nexus in the specification as filed. The examples in the specification are limited. For instance, examples 1 and 2 show assays with inhibitors of electron transport complex III and V, respectively, which inhibit collagen proteoglycan synthesis *in vitro*, and example 3 shows the *in vitro* inhibition of the ability of TGF-beta to stimulate chondrocyte functions by inhibitors of electron transport *in vitro*. The other examples disclosed in the specification relate to more *in vitro* data involving the inhibition of the production of inorganic phosphate, example 4, and the effect of inhibitors of mitochondrial function *in vitro* on calcium deposition on an artificial matrix. Evidently, none of the examples establish the required nexus between mitochondrial activity including ATP synthesis and agents for the treatment of osteoarthritis in a cow. Also, Applicant's assertion that an altered rate of ATP synthesis raises questions as to how ATP synthesis relates to osteoarthritis, but also raises questions as to what an increase or decrease of ATP synthesis by a compound means to the treatment of osteoarthritis. Applicant also has not shown how one may identify a cow suspected at being at risk for having osteoarthritis. Nothing in the examples provided, indicate whether an increase or a decrease in ATP synthesis due to a test agent relates to the treatment of osteoarthritis. Thus, even after the screening of these agents one of skill in the art would be unable to use them and thus would have to engage in an undue amount of experimentation to identify agents that are useful in the treatment of osteoarthritis.

State of the prior art and unpredictability of the art

Moreover, the art also raises questions as to the nexus of mitochondrial function and osteoarthritis. For example, Tabrizi et al. (Biochem. Soc. Symp. Vol.66 1999) show a connection between mitochondrial function and neurodegenerative disease. Terkeltaub et al. (Mitochondrion vol.1 2002 pp301-319) state that "manifestations of mitochondrial diseases are diverse of variable severity and affect multiple (Schelffler 2000)...[w]e do not yet know if mitochondrial dysfunction plays a primary or secondary role, or both, in the pathogenesis of these diseases." Both these reference indicate that more research is required first to identify what the cause of these diseases before any suitable compounds for treatment of mitochondrial diseases could be found. Thus, the art fails to provide a sufficient nexus between the rate of ATP synthesis and agents for treating osteoarthritis and further indicates that an undue amount of experimentation would be required to identify agents for to this end.

On balance, based upon the unpredictability of the art, the many different diseases associated with mitochondrial malfunction, the breadth of the instant claims, and the deficiency in the examples presented in the specification, one of skill in the art would have had to rely on an undue amount of empirical experimentation to use the invention claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims recite the language "suspected of being at risk for having." This phrase is confusing and unclear. Is Applicant claiming a method for identifying an agent for treating a cow suspected of having osteoarthritis, having osteoarthritis, or at risk for osteoarthritis. Moreover, how does one identify these cows? How does one identify a cow at risk for or suspected of having osteoarthritis? This limitation includes presently healthy cows as well, cows that are ill, and cows that will never become ill. Thus, the present phrase is inherently vague and indefinite.

Claim 3 recites the limitation "the subject." There is insufficient antecedent basis for this limitation in the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
April 21, 2003


JAMES KETTER
PRIMARY EXAMINER